K132611

MAR - 6 2014

510(k) Summary

(1) **Submitter's name, address, telephone number, a contact person and date summary was prepared:**

FHC, Inc.
1201 Main Street
Bowdoin, Maine 04287
Tel: 207-666-5651
Fax: 207-666-8539
Contact: Keri Seitz
August 16, 2013

(2) **Name(s) of device:**

Proprietary/Trade Name:	Microtable System
Common Name:	Stereotaxic instrument
Classification Name:	Stereotaxic instrument (21 CFR 882.4560), Product Code (84 HAW)

(3) **Legally Marked Predicate Device to which the submitter claims substantial equivalence:**

The Microtable System is substantially equivalent to FHC, Inc.'s WayPoint™ Stereotactic System (K092192; decision date: February 12, 2010: product code HAW).

(4) **Description of device:**

The Microtable System is a patient-specific surgical adapter, designed to be secured on a skull-based anchor mounting set to hold and align surgical instruments with patient anatomy and to allow selected targets to be reached with sub-millimeter accuracy. A Microtable System comprises an assembled Microtable, mounting hardware and tools, and cleaning and sterilization cases.

The Microtable comprises the tabletop, legs, and an instrument mounting interface. The tabletop is designed specifically for the patient using the commercially available WayPoint™ Planning and Design software. This software is currently cleared by the FDA under 510(k) K092192. Once the patient-specific tabletop is designed, the file is sent FHC, Inc. or to a qualified FHC OEM that will manufacture the tabletop using a CNC (Computer Numeric Controlled) mill. Each tabletop is patient-specific by milling at least three parallel leg holes and a hole for the instrument interface in a planar sheet of polycarbonate or Ultem. A qualified technician installs legs with appropriate lengths and rigidly attaches them to the tabletop along

with the instrument interface. After fabrication and assembly, the tabletop is dimensionally verified to ensure that it meets all of the specifications and is shipped to the hospital for sterilization and use.

The Microtable is equivalent in functionality to the Platform Adapter described in the WayPoint™ Stereotactic System approved under 510(k) K092192 and is further described in the intended use.

(5) **Statement of intended use:**

The Microtable Stereotactic System is intended to be used with commercially available stereotactic systems for intra-cranial and neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the cranium, brain, or nervous system.

(6) **Comparison of Technological Characteristics to Predicate Device:**

The Microtable System consists of several components that work together to become a stereotactic system. These components are:

1) Microtable (specific to each patient)
2) Device mounting hardware for the Platform

Like the Platform Adaptor in the predicate WayPoint™ Stereotactic System, the Microtable is a passive fixture that is specific for a given patient with no adjustments required – or possible – in the operating room. While an attached instrument may allow for adjustments relative to the fixture, the fixture itself is fixed relative to the patient's head and is immutable.

A second crucial similarity to the Platform Adaptor is that the shape of the Microtable is determined before surgery by the position of fiducial markers, the patient's anatomy, and by a trajectory defined by desired entry and target points chosen by the neurosurgeon. This determination is accomplished through a pre-operative planning stage. Three or more anchors are implanted pre-operatively, and then a pre-operative CT is acquired that includes those anchors and the targeted region of the brain. The choice of trajectory is made by the neurosurgeon while reviewing the pre-operative CT image and a pre-operative MR image of the patient using the commercially available WayPoint™ Planning and Design software, which allows for loading images, determining the positions of anchors, selecting the entry and target, and specifying the positions of three standard anatomical features, namely the anterior commisure (AC), the posterior commisure (PC) and a mid-plane point (MP) on the mid-plane of the brain.

A third similarity is that the Microtable is fixed to the patient's head via bone-mounted anchors, such as the WayPoint™ Stereotactic Anchor System

defined in the predicate device or other commercially available fiducial anchor or marker system.
One of the technological differences between the Microtable and predicate device is the material. The material differences are all non-patient contacting materials. Sterilization, stability, load and accuracy testing have been performed to show that the material differences have no effect on the safety or efficacy of the device and that the Microtable is functionally substantially equivalent to the predicate device.

The Microtable is substantially equivalent to the WayPoint™ Stereotactic System Platform Adapter, which is described in the WayPoint™ Stereotactic System approved under 510(k) K092192 and is the predicate device used in this submission. The Microtable System is substantially equivalent to the predicate device in design, intended use, and performance characteristics.

(7) **Nonclinical Performance Data:**

The following nonclinical testing was conducted in order to evaluate the accuracy and performance characteristics of the Microtable System.

- Dimensional Stability (Pre and Post Sterilization) to show the platform does not dimensionally change after sterilization. **PASS**

  Based on the dimensional stability of the device after sterilization, it is concluded that the Microtable is substantially equivalent to the predicate device which is sterilized by the same process.

- Load Testing to show that the deflection of the device is within specification when a load is applied.
  PASS

  The load testing of the Microtable meets the same specifications as the predicate device and is therefore substantially equivalent.

- Targeting Error (Accuracy) to show the accuracy of the device to a target.
  PASS

  The Targeting Error (Accuracy) of the Microtable meets the same accuracy specifications (less than 1mm) as the predicate device and is therefore substantially equivalent.

The nonclinical performance data (dimensional stability, load testing and target error – accuracy) shows that the Microtable System is as safe, as effective and performs as well as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 6, 2014

Fred Haer Company, Inc.
Ms. Keri Seitz, President and CEO
1201 Main Street
Bowdoin, ME 04287

Re: K132611
Trade/Device Name: Microtable System
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: HAW
Dated: January 24, 2014
Received: February 3, 2014

Dear Ms. Seitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K132611

Device Name
Microtable System

Indications for Use *(Describe)*
The Microtable System is intended to be used with commercially available stereotactic systems for intra-cranial and neurosurgical procedures which require the accurate positioning of microelectrodes, stimulating electrodes, or other instruments in the cranium, brain, or nervous system.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joyce M. Whang -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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